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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,708	02/09/2004	Kenneth Beaman	112461-021	9549

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EXAMINER	
RINAUDO, JO ANN S	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/774,708	BEAMAN, KENNETH	
	Examiner	Art Unit	
	Jo Ann Rinaudo	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-122 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-122 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

2. Claims 1-4, link(s) inventions I-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-4. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

I. Claims 5, 6, 15, 16, 34 and 35 drawn to a **method of immune activation** by inhibiting RTF activity, in a human, using an **antagonist to RTF**, wherein the antagonist is an **antibody** classified in class 424, subclass 130.1.

II. Claims 7-9, 16, 34 and 35 drawn to a **method of immune activation** by inhibiting RTF activity, in a human, using an **antagonist to RTF**, wherein the antagonist is an **antisense nucleic acid**, classified in class 514, subclass 44.

III. Claims 7, 10-16, 34 and 35 drawn to a **method of immune activation** by inhibiting RTF activity, in a human, using an **antagonist to RTF**, wherein the antagonist is a **small interference RNA**, classified in class 514, subclass 44.

IV. Claims 17-35 drawn to a **method of inhibiting inflammation** by **administering RTF** to a human, classified in class 424, subclass 85.1.

V. Claims 36, 37, 49-51 drawn to a **method of treating** ovarian cancer, in a human, using an **antagonist to RTF**, wherein the antagonist is an **antibody** classified in class 424, subclass 130.1.

VI. Claims 36, 38-40 and 49-51 drawn to a **method of treating** ovarian cancer, in a human, using an **antagonist to RTF**, wherein the antagonist is an **antisense nucleic acid**, classified in class 514, subclass 44.

VII. Claims 36, 38, 41, 44-51 drawn to a **method of treating** ovarian cancer, in a human, using an **antagonist to RTF**, wherein the antagonist is a **small interference RNA**, classified in class 514, subclass 44.

VIII. Claims 52-84 drawn to a **method of treating an inflammatory disorder**, wherein the inflammatory disorder is arthritis, by **administering RTF** and a TNF-a antagonist, to a human, classified in class 424, subclass 85.1.

IX. Claims 85-88 and 90-96 drawn to a **composition** of a RTF antagonist, wherein the RTF antagonist is an **antibody**, classified in class 530, subclass 387.1.

X. Claims 85-88 and 90-96 drawn to a **composition** of a RTF antagonist, wherein the RTF antagonist is a **small interference RNA**, classified in class 536, subclass 24.5.

XI. Claim 97 drawn to a composition of a RTF antagonist, classified in class 424, subclass 85.1 and class 536, subclass 24.5.

XII. Claims 98-122 drawn to a composition of RTF or fragment thereof, classified in class 530, subclass 351.

3. Groups I-VIII and Groups IX-XII are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used for affinity purification, the antisense RNA and small interference RNA can be used as a probe in hybridization, in addition to the methods of treating recited.

4. Groups I-III and V-VII and Groups IV and VIII are different methods. Groups I-III are a method of enhancing an immune response by using an antagonist to RTF, while Groups IV and VIII are a method of inhibiting inflammation by administering RTF. The methods differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

5. Groups I-III and Groups V-VII are different methods. Groups I-III are a method of enhancing an immune response by using an antagonist to RTF, while Groups V-VII are a method of treating ovarian cancer with an antagonist to RTF. The methods differ with respect to method steps, and endpoints; therefore, each method is patentably distinct.

6. Groups I-III are different methods. Antibodies, antisense RNA and small interference RNA differ with respect to their structures, physicochemical properties and modes of action; therefore each product is patentably distinct.

7. Groups V-VII are different methods. Antibodies, antisense RNA and small interference RNA differ with respect to their structures, physicochemical properties and modes of action; therefore each product is patentably distinct.

8. Groups IV and VIII are different methods. Group IV is a method of inhibiting inflammation with RTF. Group VIII is a method of treating arthritis with RTF and a TNF antagonist. The methods differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

9. Groups IX-XII are different products. Group IX is an antibody that functions as a RTF antagonist. Group X is a small interference RNA that functions as a RTF antagonist. Group XI is a non-specific RTF antagonist. Group XII is a RTF molecule or fragment thereof. Antibodies, small interference RNA and the RTF molecule differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

10. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

Species Election

11. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

12. If Group IV is elected, applicant is required to elect the following species.

A.) Applicant is required to elect a specific mammalian cell, from which the RTF or its fragment are isolated or purified, from the specific mammalian cells recited in claims 21-29, 32 or 33. These species are distinct because the cell types differ with respect to their characteristics and functions, therefore each cell type represents patentably distinct subject matter.

AND

B.) In addition to **A**, the applicant is further required to elect a specific RTF molecule, from the specific RTF molecules recited in claims 30 or 31. These species are distinct because the molecules are distinct, each has a different molecular weight and therefore represents patentably distinct subject matter.

13. If Group VIII is elected, applicant is required to elect the following species.

C.) Applicant is required to elect a specific mammalian cell, from which the RTF or its fragment are isolated or purified, from the specific mammalian cells recited in claims 54-62, 65 or 66. These species are distinct because the cell types differ with respect to their characteristics and functions, therefore each cell type represents patentably distinct subject matter.

AND

D.) In addition to **C**, the applicant is further required to elect a specific RTF molecule, from the specific RTF molecules recited in claims 63 or 64. These species are distinct because the molecules are distinct, each has a different molecular weight and therefore represents patentably distinct subject matter.

AND

E.) In addition to **C** and **D**, the applicant is further required to elect a specific target cell, from the specific target cells recited in claims 70, 71, or 72.

These species are distinct because the cell types with different characteristics and functions, therefore each cell type represents patentably distinct subject matter.

AND

F.) In addition to **C**, **D**, and **E**, the applicant is further required to elect a specific TNF-a antagonist molecule, from the specific TNF-a antagonist molecules recited in claims 78-83 or 84. These species are distinct because the TNF-a antagonists are different molecules with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

14. If Group XII is elected, applicant is required to elect the following species.

G.) Applicant is required to elect a specific mammalian cell, from which the RTF or its fragment are isolated or purified, from the specific mammalian cells recited in claims 100-108, 111 or 112. These species are distinct because the cell types differ with respect to their characteristics and functions, therefore each cell type represents patentably distinct subject matter.

AND

H.) In addition to **G**, the applicant is further required to elect a specific RTF molecule, from the specific RTF molecules recited in claims 109 or 110. These species are distinct because the molecules are distinct, each has a different molecular weight and therefore represents patentably distinct subject matter.

AND

I.) In addition to **G** and **H**, the applicant is further required to elect a specific target cell, from the specific target cells recited in claims 116, 117, or 118. These species are distinct because the cell types with different characteristics and functions, therefore each cell type represents patentably distinct subject matter.

15. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

16. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument

that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

17. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

18. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

19. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

20. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

21. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jo Ann Rinaudo whose telephone number is 571.272.8143. The examiner can normally be reached on M-F, 8:30AM - 5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571.272.0841. The fax phone number for the organization where this application or proceeding is assigned is 571.273.8300.

24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER
9/1/05

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8/26/2005